This Patient Group Direction (PGD) must only be used by registered healthcare professionals who have been named and authorised by their organisation to practice under it. The most recent and in date final signed version of the PGD should be used.

PATIENT GROUP DIRECTION (PGD)

Supply and/or administration of ulipristal acetate 30mg tablet for emergency contraception

in Community Pharmacies across BNSSG

Version Number 2.0

Change History	
Version and Date	**Change details**
Version 1.0 March 2020	New template
Version 2.0 March 2023	Updated template (no clinical changes to expired V1)

Reference Number: V2.0
Valid from: 1st March 2023
Review date: September 2025
Expiry date: 28th February 2026

PGD DEVELOPMENT GROUP

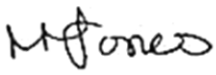
Date PGD template comes into effect:	1st March 2023
Review date	September 2025
Expiry date:	28th February 2026

This PGD template has been peer reviewed by the Reproductive Health PGDs Short Life Working Group in accordance with their Terms of Reference. It has been approved by the Faculty for Sexual and Reproductive Health (FSRH) in October 2022.

This section MUST REMAIN when a PGD is adopted by an organisation.

Name	Designation
Dr Cindy Farmer	Chair General Training Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Michelle Jenkins	Advanced Nurse Practitioner, Clinical Standards Committee Faculty of Sexual and Reproductive Healthcare (FSRH)
Vicky Garner	Deputy Chief Midwife British Pregnancy Advisory Service (BPAS)
Gail Rowley	Quality Matron British Pregnancy Advisory Service (BPAS)
Katie Girling	British Pregnancy Advisory Service (BPAS)
Julia Hogan	CASH Nurse Consultant MSI Reproductive Choices
Kate Devonport	National Unplanned Pregnancy Association (NUPAS)
Chetna Parmar	Pharmacist adviser Umbrella
Helen Donovan	Royal College of Nursing (RCN)
Carmel Lloyd	Royal College of Midwives (RCM)
Clare Livingstone	Royal College of Midwives (RCM)
Kirsty Armstrong	National Pharmacy Integration Lead, NHS England
Dipti Patel	Local authority pharmacist
Emma Anderson	Centre for Postgraduate Pharmacy Education (CPPE)
Dr Kathy French	Specialist Nurse
Dr Sarah Pillai	Associate Specialist
Alison Crompton	Community pharmacist
Andrea Smith	Community pharmacist
Lisa Knight	Community Health Services pharmacist
Bola Sotubo	NHS North East London ICB pharmacist
Tracy Rogers	Director, Medicines Use and Safety, Specialist Pharmacy Service
Sandra Wolper	Associate Director Specialist Pharmacy Service
Jo Jenkins (Woking Group Co-ordinator)	Lead Pharmacist PGDs and Medicine Mechanisms Specialist Pharmacy Service

ORGANISATIONAL AUTHORISATIONS AND OTHER LEGAL REQUIREMENTS

Name	Job title and organisation	Signature	Date
Dr Lindsey Harryman	**Consultant in Genitourinary Medicine Unity Sexual Health**		28.02.23
Debbie Campbell	**Deputy Director (Medicines Optimisation) Bristol, North Somerset and South Gloucestershire ICB**		27.02.23
Senior representative of professional group using the PGD	**Michelle Jones Principal Medicines Optimisation Pharmacist Bristol, North Somerset and South Gloucestershire ICB**		23.02.23
Public Health Representative in Bristol City Council	**Christina Gray Director of Public Health for Bristol**		27.02.23
Public Health Representative in North Somerset Council	**Matt Lenny Director of Public Health for North Somerset**		28.02.23
Public Health Representative South Gloucestershire Council	**Prof. Sarah Weld Director of Public Health for South Gloucestershire**		23.02.23

1. Characteristics of staff

Qualifications and professional registration	Registered pharmacist with current GPhC registration. Currently employed or working as a locum pharmacist in a community pharmacy in Bristol, North Somerset or South Gloucestershire.
Initial training	The registered healthcare professional authorised to operate under this PGD must have undertaken appropriate education and training and successfully completed the competencies to undertake clinical assessment of patients ensuring safe provision of the medicines listed in accordance with local policy. Must have completed the following e-learning modules within the last 3 years: 1. The CPPE EHC e-learning and assessment module 2. The e-lfh Emergency Contraception session of the Sexual and Reproductive Healthcare course. 3. The e-lfh Raising awareness of Child Sexual Exploitation e-learning course. The healthcare professional must have completed the CPPE Safeguarding Children and adults e-learning and e-assessment module within the last 2 years.
Competency assessment	• Individuals operating under this PGD must be assessed as competent (see Appendix A) or complete a self-declaration of competence for emergency contraception. • Staff operating under this PGD are encouraged to review their competency using the NICE Competency Framework for health professionals using patient group directions
Ongoing training and competency	• Individuals operating under this PGD are personally responsible for ensuring that they remain up to date with the use of all medicines and guidance included in the PGD - if any training needs are identified these should be addressed and further training provided as required. • Organisational PGD and/or medication training as required by employing Trust/organisation.
The decision to supply any medication rests with the individual registered health professional who must abide by the PGD and any associated organisational policies.	

2. Clinical condition or situation to which this PGD applies

Clinical condition or situation to which this PGD applies	To reduce the risk of pregnancy after unprotected sexual intercourse (UPSI) or regular non-hormonal contraception has been compromised or used incorrectly.
Criteria for inclusion	• Any female-bodied individual up to and including 24 years, presenting for emergency contraception (EC) between 0 and up to and including 120 hours following UPSI or when regular non-hormonal contraception has been compromised or used incorrectly. • Ulipristal should be considered first line if UPSI is likely to have taken place during the 5 days prior to ovulation (high risk) • In exceptional circumstances, the Pharmacist may use their professional judgement to supply to vulnerable patients over 24 years if patients are not able to access emergency contraception via other routes. • To re-treat a patient who has vomited within three hours of taking ulipristal emergency contraception (UPA-EC) and is still within 120 hours of UPSI. • Informed consent given. • No contraindications to the medication.
Criteria for exclusion	• Informed consent not given. • The individual wishes to see a doctor or nurse • Individuals under 16 years old and assessed as lacking capacity to consent using the Fraser Guidelines. • Individuals 16 years of age and over and assessed as lacking capacity to consent. • This episode of UPSI occurred more than 120 hours ago. N.B. A dose may be given if there have been previous untreated or treated episodes of UPSI within the current cycle if the most recent episode of UPSI is within 120 hours. • Known pregnancy (N.B. a previous episode of UPSI in this cycle is not an exclusion. Consider pregnancy test if more than three weeks after UPSI and no normal menstrual period). • Less than 21 days after childbirth. • Less than 5 days after miscarriage, abortion, ectopic pregnancy or uterine evacuation for gestational trophoblastic disease (GTD). • Known hypersensitivity to the active ingredient or to any component of the product - see Summary of Product Characteristics • Use of levonorgestrel (LNG-EC) or any other progestogen in the previous 7 days (i.e. hormonal contraception, hormone replacement therapy or use for other gynaecological indications). Consider referral for Cu-IUD. • Concurrent use of antacids, proton-pump inhibitors or H_2-receptor antagonists including any non-prescription (i.e. over the counter) products being taken • Severe asthma controlled by oral glucocorticoids. • Individuals using enzyme-inducing drugs/herbal products

Criteria for exclusion continued	or within 4 weeks of stopping. • Acute porphyria
Cautions including any relevant action to be taken	• All individuals should be informed that insertion of a copper intrauterine device (Cu-IUD) within five days of UPSI or within five days from earliest estimated ovulation is the most effective method of emergency contraception. If a Cu-IUD is appropriate and acceptable supply oral EC and refer to Unity Sexual Health Services via PharmOutcomes. • Ulipristal acetate can delay ovulation until closer to the time of ovulation than levonorgestrel. Therefore, Ulipristal should be considered first line if the individual presents in the five days leading up to estimated day of ovulation. • Ulipristal acetate (UPA-EC) is ineffective if taken after ovulation. • If individual vomits within three hours from ingestion, a repeat dose may be given. If the individual vomits within three hours following administration of a dose but is subsequently outside of the 120-hour window for treatment a repeat dose is unlikely to be effective, and they should be referred to Unity Sexual Health Service or their GP for consideration of a Cu-IUD. • Body Mass Index (BMI) >26kg/m2 or weight >70kg – individuals should be advised that though oral EC methods may be safely used, a high BMI may reduce the effectiveness. A Cu-IUD should be recommended as the most effective method of EC. • Consideration should be given to the current disease status of those with severe malabsorption syndromes, such as acute/active inflammatory bowel disease or Crohn's disease. Although the use of UPA-EC is not contra-indicated it may be less effective and so these individuals should be advised that insertion of Cu-IUD would be the most effective emergency contraception for them and referred accordingly if agreed. • Breast feeding – advise to express and discard breast milk for 7 days after UPA-EC dose. • The effectiveness of UPA-EC can be reduced by progestogen taken in the following 5 days and individuals must be advised not to take progestogen containing drugs for 5 days after UPA-EC. UPA EC is generally not recommended in a missed pill situation. See section 'Written information and further advice to be given to individual'. • If the individual is less than 16 years of age an assessment based on Fraser guidelines must be made and documented. • With all people, but particularly with the young or vulnerable, be satisfied that sexual intercourse has been consensual and is not occurring in an abusive relationship. If non-consensual sex or sexual abuse is suspected, follow local safeguarding policy. • If the individual is less than 13 years of age the healthcare professional should speak to local

Cautions including any relevant action to be taken continued	safeguarding lead and follow the local safeguarding policy. • If the individual has not yet reached menarche consider onward referral for further assessment or investigation. • Active trophoblastic disease – seek advice from Unity Sexual Health Service
Action to be taken if the individual is excluded or declines treatment	• Explain the reasons for exclusion to the individual and document in the consultation record. • Record reason for decline in the consultation record. • Offer suitable alternative emergency contraception or refer the individual as soon as possible to Unity Sexual Health (0117 342 6900) or their GP practice. The PharmOutcomes consultation record can be used to automatically refer individuals for an emergency coil subject to the individual's consent being obtained. Information about further options should also be provided

3. Description of treatment

Name, strength & formulation of drug	Ulipristal acetate 30mg tablet
Legal category	P
Route of administration	Oral
Off label use	Best practice advice given by Faculty of Sexual and Reproductive Healthcare (FSRH) is used for guidance in this PGD and may vary from the Summary of Product Characteristics (SPC). This PGD includes off-label use in the following conditions: • Lapp-lactase deficiency • Hereditary problems of galactose intolerance • Glucose-galactose malabsorption • Severe hepatic impairment Medicines should be stored according to the conditions detailed in the Storage section in this table. However, in the event of an inadvertent or unavoidable deviation of these conditions the local pharmacy or Medicines Management team must be consulted. Where drugs have been assessed by pharmacy/Medicines Management in accordance with national or specific product recommendations as appropriate for continued use this would constitute off-label administration under this PGD. The responsibility for the decision to release the affected drugs for use lies with pharmacy/Medicines Management. Where a drug is recommended off-label consider, as part of the consent process, informing the individual/parent/carer that the drug is being offered in accordance with national guidance but that this is outside the product licence.
Dose and frequency of administration	• One tablet (30mg) as a single dose taken as soon as possible up to 120 hours after UPSI.

Duration of treatment	• A single dose is permitted under this PGD.
	• If vomiting occurs within 3 hours of UPA-EC being taken a repeat dose can be supplied under this PGD.
	• Repeated doses, as separate episodes of care, can be given within the same cycle. Please note:
	  ○ If within 7 days of previous LNG-EC offer LNG-EC again (not UPA-EC)
	  ○ If within 5 days of UPA-EC then offer UPA-EC again (not LNG-EC)

Quantity to be supplied	Appropriately labelled pack of one tablet. Note: it is strongly recommended the dose is taken at the time of consultation. If the individual declines a labelled supply may be provided and individual should be advised to take as soon as possible and ensure it is within the 120-hour window.
Storage	Medicines must be stored securely according to national guidelines and in accordance with the product SPC.

Drug interactions	A detailed list of drug interactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk or the BNF www.bnf.org Refer also to FSRH guidance on drug interactions with hormonal contraception FSRH CEU Guidance: Drug Interactions with Hormonal Contraception (May 2022) - Faculty of Sexual and Reproductive Healthcare
Identification & management of adverse reactions	A detailed list of adverse reactions is available in the SPC, which is available from the electronic Medicines Compendium website: www.medicines.org.uk and BNF www.bnf.org The following side effects are common with UPA-EC (but may not reflect all reported side effects): • Nausea or vomiting • Abdominal pain or discomfort • Headache • Dizziness • Muscle pain (myalgia) • Dysmenorrhea • Pelvic pain • Breast tenderness • Mood changes • Fatigue • The FSRH advises that disruption to the menstrual cycle is possible following emergency contraception.
Management of and reporting procedure for adverse reactions	• Healthcare professionals and patients/carers are encouraged to report suspected adverse reactions to the Medicines and Healthcare products Regulatory Agency (MHRA) using the Yellow Card reporting scheme on: http://yellowcard.mhra.gov.uk • Record all adverse drug reactions (ADRs) in the patient's medical record. • Report any adverse reactions via organisation incident policy. **Anaphylaxis** Before administering any medication, the possibility of anaphylaxis must be considered and appropriate medical treatment should be available for immediate use in case of anaphylactic reactions. For further information, please see the resuscitation council guidelines. http://www.resus.org.uk/pages/glalgos.htm http://www.resus.org.uk/pages/reaction.pdf

Written information and further advice to be given to individual	• All methods of emergency contraception should be discussed. All individuals should be informed that fitting a Cu-IUD within five days of UPSI or within five days from the earliest estimated ovulation is the most effective method of emergency contraception. Refer to Unity for CuIUDs through PharmOutcomes. • Those wanting a referral for a Cu-IUD should still be offered emergency hormonal contraception, if appropriate. • Pregnancy is theoretically possible after UPSI on most days of the cycle. However, risk of pregnancy is highest after UPSI that takes place during the 6 days leading up to and including the day of ovulation. In the days immediately prior to ovulation and on the day of ovulation itself, pregnancy risk following a single episode of UPSI has been estimated to be up to 30%. Pregnancy is extremely unlikely to occur as a result of UPSI in the first 3 days of a natural menstrual cycle • The possible mechanisms of action should be explained to the individual as some methods may not be acceptable, depending on individual beliefs about the onset of pregnancy and abortion. • UPA-EC acts by delaying ovulation for at least 5 days, until sperm from the UPSI for which EC was taken are no longer viable. UPA-EC delays ovulation even after the luteinising hormone (LH) surge whereas LNG-EC is no longer effective after the start of the LH surge. • In the late follicular phase, however, LNG-EC becomes ineffective while UPA-EC is still able to delay ovulation. • Neither UPA-EC and LNG-EC are effective post-ovulation • Inform the individual that the majority of women will go on to ovulate later in the cycle and are therefore at risk of pregnancy from subsequent UPSI. Individuals should be made aware of this risk regarding ongoing contraception • Ensure that a patient information leaflet (PIL) is provided within the original pack. • If vomiting occurs within three hours of taking the dose, the individual should return for another dose. • Explain that menstrual disturbances can occur after the use of emergency hormonal contraception. • Provide advice on ongoing contraceptive methods, including how these can be accessed. Refer to Unity Sexual Health Clinic or GP practice if appropriate. • Repeated episodes of UPSI within one menstrual cycle - the dose may be repeated more than once in the same menstrual cycle should the need occur. • In line with FSRH guidance individuals using hormonal contraception should delay restarting their regular hormonal contraception for 5 days following UPA-EC use. Avoidance of pregnancy risk (i.e. use of condoms or abstain from intercourse) should be advised until fully effective.

Written information and further advice to be given to individual continued	• Advise a pregnancy test three weeks after treatment especially if the expected period is delayed by more than seven days or abnormal (e.g. shorter or lighter than usual), or if using hormonal contraception which may affect bleeding pattern. • Promote the use of condoms to protect against sexually transmitted infections (STIs) and advise on the possible need for screening for STIs. • Offer a condom supply pack free of charge to every patient aged 24 and under requesting EHC. • For ongoing condom supplies advise young people condoms are freely available through the C-Card scheme: C card in Bristol, North Somerset and South Gloucestershire | Unity Sexual Health. • As part of raising awareness around sexually transmitted infections and to increase Chlamydia screening uptake, all clients presenting for UPA-EC should be informed that it does not protect against sexually transmitted infections and should be offered a Chlamydia screening kit and advised how to submit it for testing. • There is no evidence of harm if someone becomes pregnant in a cycle when they had used emergency hormonal contraception. • Advise to consult a pharmacist, nurse or doctor before taking any new medicines including those purchased. • Consider the FSRH CEU Statement: Contraceptive Choices and Sexual Health for Transgender and Non-Binary People (2017) where appropriate.
Advice / follow up treatment	• The individual should be advised to seek medical advice in the event of an adverse reaction. • The individual should attend an appropriate health service provider if their period is delayed, absent or abnormal or if they are otherwise concerned. • Pregnancy test as required (see advice to individual above). • Individuals advised how to access on-going contraception and STI screening as required. • All individuals presenting for emergency contraception should be supplied with a screening kit for chlamydia. If sexually transmitted infection is suspected, refer the individual to their GP practice or Unity Sexual Health Service (0117 342 6900). • If individuals cannot be treated under this PGD or wish to have an emergency Cu-IUD fitted, they can be automatically referred to Unity Sexual Health via completion of the PharmOutcomes consultation record, provided patient consent is obtained.

Records	Record the supply in the patient's medication records, and the below information onto PharmOutcomes in line with the service protocol. Following the PharmOutcomes template will result in all of the required information being recorded
	
	Record:
	• The consent of the individual and
	  ○ If individual is under 13 years of age record action taken
	  ○ If individual is under 16 years of age document capacity using Fraser guidelines. If not competent record action taken.
	  ○ If individual over 16 years of age and not competent, record action taken
	• Name of individual, address, date of birth
	• GP contact details where appropriate
	• Relevant past and present medical history, including medication history. Examination finding where relevant e.g. weight
	• Any known medication allergies
	• Name of registered health professional operating under the PGD
	• Name of medication supplied
	• Date of supply
	• Dose supplied
	• Quantity supplied
	• Advice given, including advice given if excluded or declines treatment
	• Details of any adverse drug reactions and actions taken
	• Advice given about the medication including side effects, benefits, and when and what to do if any concerns
	• Any referral arrangements made
	• Any supply outside the terms of the product marketing authorisation
	• Recorded that administered/supplied via Patient Group Direction (PGD)
	
	Note: It is strongly recommended that the individual takes the dose of UPA-EC at the time of the consultation. If this is not the case, the reason why should be recorded in the individual's record.
	
	Records should be signed and dated (or a password controlled e-records) and securely kept for a defined period in line with local policy.
	
	All records should be clear, legible and contemporaneous.
	
	A record of all individuals receiving treatment under this PGD should also be kept for audit purposes in accordance with local policy.

4. Key references

Key references (accessed September 2022)	• Electronic Medicines Compendium http://www.medicines.org.uk/ • Electronic BNF https://bnf.nice.org.uk/ • NICE Medicines practice guideline "Patient Group Directions" https://www.nice.org.uk/guidance/mpg2 • Faculty of Sexual and Reproductive Health Clinical Guidance: Emergency Contraception - March 2017 (Amended March 2020) https://www.fsrh.org/standards-and-guidance/current-clinical-guidance/emergency-contraception/ • Faculty of Sexual and Reproductive Health Drug Interactions with Hormonal Contraception – May 2022 https://www.fsrh.org/documents/ceu-clinical-guidance-drug-interactions-with-hormonal/ • Royal Pharmaceutical Society Safe and Secure Handling of Medicines December 2018 https://www.rpharms.com/recognition/setting-professional-standards/safe-and-secure-handling-of-medicines

Appendix A – Example registered health professional authorisation sheet
PGD Name/Version: UPA-EC PGD v2.0 Valid from: Mar 23 Expiry: Feb 26

Before signing this PGD, check that the document has had the necessary authorisations. Without these, this PGD is not lawfully valid.

Registered health professional

By signing this patient group direction you are indicating that you agree to its contents and that you will work within it. Patient group directions do not remove inherent professional obligations or accountability. It is the responsibility of each professional to practise only within the bounds of their own competence and professional code of conduct.

I confirm that I have read and understood the content of this Patient Group Direction and that I am willing and competent to work to it within my professional code of conduct.			
Name	**Designation**	**Signature**	**Date**

Authorising manager

I confirm that the registered health professionals named above have declared themselves suitably trained and competent to work under this PGD. I give authorisation on behalf of insert name of organisation for the above named health care professionals who have signed the PGD to work under it.			
Name	**Designation**	**Signature**	**Date**

Note to authorising manager

Score through unused rows in the list of registered health professionals to prevent additions post managerial authorisation.
This authorisation sheet should be retained to serve as a record of those registered health professionals authorised to work under this PGD.